510(k) Summary K123228

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MAR 8 2013

DATE PREPARED: January 30, 2013

Contact: Kichul Cha, CEO

1. **Identification of the Device:**
   Proprietary-Trade Names:
   InBody770, InBody570, InBody S10, InBody H20/InBody H20Ⓑ
   Classification Names: ANALYZER, BODY COMPOSITION
   Common/Usual Name: Body fat meter
   Regulation Description: Impedance plethysmograph.
   Classification Panel: Cardiovascular
   Product Code: MNW
   Regulation Number: 870. 2770
   Classification: II

2. **Equivalent legally marketed devices: (Predicate device Information)** Biospace Body Composition Analyzer Model InBody170, Model InBodyJ30 InBodyS10 **K110689**

3. **Indications for Use** InBody770, InBody570, InBody S10, InBody H20/InBody H20Ⓑ
   For use only in healthy subjects for Measurement of:

   Estimated: Skeletal Muscle Mass, Extra-Cellular Water (ECW), Intra-Cellular Water (ICW), Total Body Water (TBW), ECW/TBW, Body Fat, Percentage of Body Fat (PBF), Body Lean + Dry Lean, Metabolic Rates(Basal Metabolic Rates), Segmental Lean Mass, Segmental Fat Mass, % Segmental Body Fat, Energy Expenditure of Activity, Visceral Fat Area (VFA), Visceral Fat Level, Segmental Body Water, Body Shape Graph

   Actual: Weight [except for Model InBodyS10, which requires the manual entry of weight], Body Mass Index (BMI) and Impedance Values, Height [except for Model InBody S10 and InBody H20/InBody H20Ⓑ, which requires the manual entry of Height], Resistance Values [only for InBody770, InBody S10], Reactance Values [for InBody770, InBody S10], Phase Angle [for InBody770, InBody S10] The InBody H20 and the InBody H20Ⓑ are identical except that the Ⓑ model has Bluetooth capability for data transfer.

4. **Description of the Device**: InBody770, InBody570, InBody S10, InBody H20/InBody H20Ⓑare impedance plethysmograph body composition analyzers. These devices determine body composition parameters based on bioelectrical impedance analysis (BIA). BIA relies on the differing behavior of biological tissues in response to an applied electrical current. Lean tissue is generally highly conductive because it contains large amounts of bound water and electrolytes, while fat tissue and bone are relatively poor conductors. By analyzing the response to electrical signals, BIA thereby permits differentiation of lean tissue, fat, and water and, in some instances, derivation of related body composition parameters. The total impedance resulting from BIA incorporates both

resistance and capacitance components. Impedance plethysmographic devices are used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs. Multi-frequency and segmental bioelectrical impedance analysis can estimate the distribution of body water (total body water; intra-cellular water; extra-cellular water), and can correlate with fluid compartmentalization. Assuming that body lean mass is hydrated in a constant and uniform manner; bioelectrical impedance analysis can be used to estimate body lean mass and fat mass. Body composition analysis results may be of value to health care professionals in their management of the relative balance and levels of fat and lean tissue. The InBody H20 and the InBody H20Ⓑ are identical except that the Ⓑ model has Bluetooth capability for data transfer.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and software testing indicates that the new devices are as safe and effective as the predicate device.

6. **Comparison Table**

Devices		InBody 170	InBody J30	InBody S10	InBody 770	InBody 570	InBody S10	InBody H20/ H20Ⓑ Ⓑ has Bluetooth data module.
510(k) number		K110689	K110689	K110689	New	New	New	New
Manufacturer		Biospace	Biospace	Biospace	Biospace	Biospace	Biospace	Biospace
Measurement of Estimated :	Extra-Cellular Water(ECW)	√	√	√	√	√	√	√
	Intra-Cellular Water (ICW)	√	√	√	√	√	√	√
	Total Body Water (TBW)	√	√	√	√	√	√	√
	Skeletal Muscle Mass	√	√	√	√	√	√	√
	Body Fat Mass	√	√	√	√	√	√	√
	Lean Body Mass	√	√	√	√	√	√	√
	Dry Lean Mass	√	√	√	√	√	√	√
	Basal Metabolic Rates	√	√	√	√	√	√	√

Devices		InBody 170	InBody J30	InBody S10	InBody 770	InBody 570	InBody S10	InBody H20/ H20Ⓑ Ⓑ has Bluetooth data module.
	Segmental Lean Mass	√	√	√	√	√	√	√
	ECW/TBW	√	√	√	√	√	√	√
	Segmental Body Fat mass	√	√	√	√	√	√	√
	% Segmental Body Fat	√	√	√	√	√	√	√
	Energy expenditure of activity	√	√	√	√	√	√	√
	Visceral Fat Area	√	√	√	√	√	√	√
	Segmental Body Water				√	√	√	√
Measurement of Actual :	Weight	√	√		√	√		√
	Height		√					
	Body Mass Index (BMI)	√	√	√	√	√	√	√
	Impedance Values	20, 100kHz	5, 50, 250kHz	1, 5, 50, 250, 500, 1,000kHz	1, 5, 50, 250, 500, 1,000kHz	5, 50, 500kHz	1, 5, 50, 250, 500, 1,000kHz	20, 100kHz
	Reactance Values			5,50,250 kHz	5,50,250 kHz		5,50,250kHz	
	Phase Angle			5,50,250kHz	5,50,250kHz		5,50,250kHz	
Measurement method		**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**

Devices		InBody 170	InBody J30	InBody S10	InBody 770	InBody 570	InBody S10	InBody H20/ H20Ⓑ Ⓑ has Bluetooth data module.
Electrode type		4 electric poles 8 points Touch type electrode measure-ment	4 electric poles 8 points Touch type electrode measure-ment	4 electric poles 8 points Touch type electrode measure-ment	4 electric poles 8 points Touch type electrode measure-ment	4 electric poles 8 points Touch type electrode measure-ment	4 electric poles 8 points Touch type electrode measure-ment	4 electric poles 8 points Touch type electrode measure-ment
Power Source		Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	DC 6V (AA type battery, 1.5V×4EA)
Equipment weight		14.3kg	29kg	2kg	38kg	24kg	2kg	2.7kg
Equipment size		396(W) X 608(L) X 955(H) : mm	360(W) X 640(L) X 2235(H) : mm	202(W) X 322(L) X 53(H): mm	526(W) X 854(L) X 1175(H): mm	522(W) X 893(L) X 1113(H): mm	202(W) X 322(L) X 53(H): mm	310.3(W) x 356.4(L) x 58.3(H) :mm
Measurement time		30 seconds	30 seconds	110 seconds	50 seconds	50 seconds	110 seconds	5 seconds
Measurement age		From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99	From age 1 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99
Measurement weight		10 ~ 250kg	10 ~ 250kg	10 ~ 250kg	10 ~ 270kg	5 ~ 250kg	10 ~ 250kg	10 ~ 200kg

7. Discussion of Non-Clinical Testing: Electromagnetic and Safety Testing was conducted to IEC 60601-1 and IEC 60601-1-2. Software validation was conducted. Literature was compiled and reviewed.

8. Discussion of Clinical Testing:

   In order to verify InBody570's clinical performance, we conducted comparison performance test between InBody570 and InBody J30 that obtained FDA premarket notification under FDA law. The test was conducted with a group of 68 examinees.

   In order to verify InBody770's clinical performance, we conducted comparison performance test between InBody770 and InBody J30. The test was conducted with 40 examinees.
   In order to verify InBody S10's clinical performance, we conducted comparison performance test between InBody S10 and InBody3.0 that obtained FDA premarket notification under FDA law. The test was conducted with a group of 43 examinees.

In order to verify InBody H20/InBody H20Ⓑ's clinical performance, we conducted comparison performance test between InBody H20/InBody H20Ⓑ and InBody J30. The test was conducted with 40 examinees.

9. Conclusion: There is only one difference in the indications for use between our new devices and our predicates: The addition of Segmental Body Water. This is based on a computation that is supported by reference papers: Segmental Body Water is calculated using Segmental Lean Mass that is already submitted in InBody J30 (K110689). Body Water can be calculated by Lean Body Mass (= Fat Free Mass) according to fact which is founded in the attached reference papers. As in papers they tell body water/fat free mass is 0.73. So, InBody using this fact can measure segmental body water from segmental lean mass (segmental fat free mass).

As compared to our predicate devices (our own brand) these new models have very similar technological characteristics and performed comparably to our predicates. The same scientific principles are used to produce the measurements. We therefore conclude that our new models are substantially equivalent to our predicates cleared in 2011.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Biospace Corporation Limited
Kamm & Associates
% Mr. Daniel Kamm
Principal Engineer
8870 Ravello Ct
NAPLES FL 34114

Re: K123228
Trade/Device Name: 1) Biospace Body Composition Analyzer, Model InBody770
2) Biospace Body Composition Analyzer, Model InBody570
3) Biospace Body Composition Analyzer, Model InBody S10
4) Biospace Body Composition Analyzer, Model InBody H20/InBody H20$^{(B)}$
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: January 30, 2013
Received: February 5, 2013

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123228

Device Name:

1) Biospace Body Composition Analyzer, Model InBody770
2) Biospace Body Composition Analyzer, Model InBody570
3) Biospace Body Composition Analyzer, Model InBody S10
4) Biospace Body Composition Analyzer, Model InBody H20/InBody H20Ⓑ

Indications for use:

For use only in healthy subjects for Measurement of:

Estimated: Skeletal Muscle Mass, Extra-Cellular Water (ECW), Intra-Cellular Water (ICW), Total Body Water (TBW), ECW/TBW, Body Fat, Percentage of Body Fat (PBF), Body Lean + Dry Lean, Metabolic Rates(Basal Metabolic Rates), Segmental Lean Mass, Segmental Fat Mass, % Segmental Body Fat, Energy Expenditure of Activity, Visceral Fat Area (VFA),.Visceral Fat Level, Segmental Body Water, Body Shape Graph

Actual: Weight [except for Model InBodyS10, which requires the manual entry of weight], Body Mass Index (BMI) and Impedance Values, Height [except for Model InBody S10 and InBody H20/InBody H20Ⓑ, which requires the manual entry of Height], Resistance Values [only for InBody770, InBody S10], Reactance Values [for InBody770, InBody S10], Phase Angle [for InBody770, InBody S10]. The InBody H20 and the InBody H20Ⓑ are identical except that t he Ⓑ model has Bluetooth capability for data transfer.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123228